

INTRODUCTION

Blood STASIS-CTC Tube is used for collecting whole blood and for isolating circulating, cell-free tumor cells (CTC) from blood. It is a plastic, evacuated tube. The tube has a non-fixative additive inside that helps maintain the viability of blood cells including tumor cells and also helps prevent the coagulation of whole blood.

INTENDED USE

Blood STASIS-CTC Tube is intended for collection, stabilization, transportation and storage of whole blood for subsequent isolation of circulating cell-free tumor cells from blood. Blood STASIS CTC Tube has to be used for research purposes only. Molecular and immune-oncology testing methods that need CTC are its suggested use.

Do not use Blood STASIS-CTC tube for managing patients and diagnostic procedures.

The clinical utility and the performance characteristics of this product have not been established for in vitro diagnostic procedure.

PRODUCT FEATURES	Blood STASIS-CTC 9mL (BS-CT10-100)	Blood STASIS-CTC 6mL (BS-CT6-100)	Blood STASIS-CTC 3mL (BS-CT3-200)
Tube Size	16 x 100mm	13 x 100mm	13 x 75mm
Blood draw volume	8 ml	5.4 ml	2.65 ml
Additive volume	1 ml	0.6 ml	0.35 ml
Sample stability	upto 7 days	upto 7 days	upto 7 days
Sample Storage Temperature	15°C-30°C	15°C-30°C	15°C-30°C
Quantity of tubes	100	100	200

Blood STASIS™-CTC is for Research Use Only. Not for use in diagnostic procedures. No claim or representation is intended to provide information for the diagnosis, prevention, or treatment of a disease. The performance characteristics of this product have not been fully established.

SUMMARY

The Blood STASIS-CTC product comprising of a single tube, delivers an effective method for standardization of blood collection, transport and storage of whole blood sample, preservation of cfDNA.

PRINCIPLE OF PROCEDURE

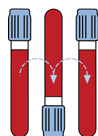
Blood STASIS-CTC tube allows the collection from 2.65ml to 8ml (depending on the product) of whole blood in a closed, evacuated system. Blood is collected using standard venipuncture technique into an evacuated tube that contains either 0.35ml, 0.6ml or 1ml of cell stabilization additive

SPECIMEN COLLECTION AND PREPARATION FOR ANALYSIS

- Required Blood Collection Accessories (not included with Blood STASIS-CTC Tube).
- Collect specimen by venipuncture
- If required, use labels for sample identification.
- For the cleaning site, use alcohol swab.
- Dry Sterile Gauze
- Tourniquet is used.
- A biohazard container is used for used needle or needle/holder combination.

PROCEDURE FOR SPECIMEN COLLECTION

1. Blood STASIS-CTC tube should be properly labeled with sample identification and be at room temperature before use.
 2. Collection of blood in the tube is done using the SOP for venipuncture technique used in customer's laboratory.
 3. Preventing back flow:
 - To guard against back flow, observe the following precautions:
 - a. Keep patient's arm in the downward position during the collection procedure.
 - b. Hold the tube with the stopper in the uppermost position so that the tube contents do not touch the stopper or the end of the needle during sample collection.
 - c. Release tourniquet once blood starts to flow in the tube, or within 2 minutes of application.
 - d. Make sure tube additives do not touch stopper or non-patient end of the needle during venipuncture.
 4. Before removing the tube from the holder it should be ensured that the blood flow into the tube has stopped.
 5. Fill Blood STASIS-CTC tube to the indicated line on the tube.
 6. Invert the tube 8 to 10 times gently to allow efficient stabilization of specimen.
- Regardless of the additive type, all tubes should be gently inverted to ensure thorough mixing of the blood with the additive. Tubes must be mixed to ensure that the specimen does not clot.



7. Blood samples filled in Blood STASIS-CTC tube are stable at room temperature (15–30°C) for up to 7 days until centrifugation and plasma processing.

Practice Universal Precautions. Use gloves, gowns, eye protection, other personal protective equipment, and engineering controls to protect from blood splatter, blood leakage, and potential exposure to blood borne pathogens.

Handle all biologic samples and blood collection devices (lancets, needles, lue adapters, and blood collection sets) according to the policies and procedures of your facility. Obtain appropriate medical attention in the event of any exposure to biologic samples (for example, through a puncture injury), since they may transmit viral hepatitis, HIV, or other infectious diseases.

Discard all blood collection tubes and accessories in biohazard containers approved for their disposal. Since this Blood STASIS-CTC tube contains a chemical additive, precautions should be taken to prevent possible back flow from the tube during drawing of blood (see Procedure for Specimen Collection).

Transferring a blood sample collected with a syringe and needle into the Blood STASIS-CTC tubes is not recommended due to the increased potential for needle stick injury.

- Do not re-use Blood STASIS-CTC tube. For single use only.
- Do not use Blood STASIS-CTC tube after expiration date.
- Do not freeze blood sample collected in Blood STASIS-CTC tube.
- Do not use injected contents of Blood STASIS-CTC tube content on patients.
- Do not add any other component to Blood STASIS-CTC tube.

ORDERING AND TECHNICAL ASSISTANCE

To place an ordering and technical assistance, call 301-302-0144 or visit our website at www.magbiogenomics.com.

STORAGE AND STABILITY

1. Store the unused Blood STASIS-CTC tubes at room temperature (15–30°C) for 12 months.
2. Blood samples collected in Blood STASIS-CTC tube for CTC analysis are stable for 7 days when stored between (15–30°C).

Since Blood STASIS-CTC tubes contain a chemical additive, it is important to avoid possible backflow from the tube, with the possibility of adverse subject reactions. To guard against backflow, observe the following precautions.

1. Place subject's arm in a downward position.
2. Hold tube with the stopper uppermost.
3. Release tourniquet as soon as blood starts to flow into tube.
4. Make sure tube additives do not touch stopper or non-patient end of the needle during venipuncture.

LIMITATIONS OF SYSTEM

1. This Blood STASIS-CTC tube is for research use only, and therefore, the use of this product for diagnostic procedures and subject management is strictly prohibited. Neither the clinical utility nor the performance characteristics of Blood STASIS-CTC tube and kits as part of an in vitro diagnostic procedure have been established.
2. The quantity of blood drawn varies with altitude, ambient temperature, barometric pressure, tube age, venous pressure, and filling technique.
3. Endotoxin not controlled. Blood and blood components collected and processed in the tube are not intended for infusion or introduction into the human body.

PRECAUTIONS

- Contents of this tube may cause irritation to eyes, respiratory system and skin.
- After inhalation, supply fresh air, and seek medical advice in case of complaints.
- After skin contact, immediately wash with water and soap and rinse thoroughly.
- After eye contact, rinse immediately with plenty of water for at least 15 minutes and seek medical advice.
- After swallowing, immediately seek medical advice.